on page 2, line 30 to page 3, line 9 provides support for the amendment to claim 2. Applicants have amended claims 9 and 12 to conform to U.S. patent practice. Applicants have amended claims 10, 11, and 13 to correct dependency and subordinate claims to independent claims 9 or 12.

New claims 14-17 find support in original filed claims 1-3 and claim 9. Applicants have not raised any issue of new matter.

Conclusion

Applicants respectfully submit that the present application claims patentable subject matter and is in condition for allowance.

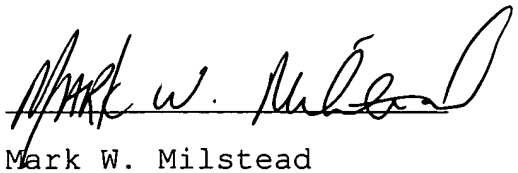
Attached hereto is a marked-up version of the changes made to this application by this Preliminary Amendment.

If the Examiner believes for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (302) 934-4395, in Millsboro, Delaware.

If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any

overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17; particularly extension of time fees.

Respectfully submitted,



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Enclosure: Version with Marking to Show Changes Made

Attorney Docket Number O 2000.551 US

Version with Marking to Show Changes Made

In the Claims

Claims 4-8 have been canceled.

The claims have been amended as follows:

1. (Amended) A [combination] pharmaceutical composition, comprising:

paracetamol or a non-steroidal anti-inflammatory drug [(NSAID)], or a pharmaceutically acceptable salt or solvate thereof, [and]

[another drug, characterized in that the other drug is] mirtazapine, or a pharmaceutically acceptable salt or solvate thereof, and

optionally in association with one or more pharmaceutically acceptable carriers.

2. (Amended) The [combination] pharmaceutical composition according to claim 1, [characterized in that the combination comprises a pharmaceutical composition which comprises both mirtazapine and paracetamol or an NSAID, optionally in association with one or ore pharmaceutically acceptable carriers] wherein said non-steroidal anti-inflammatory drug is selected from the group consisting of aceclofenac, antipyrine, acetylsalicylic acid, benoxaprofen, butibufen, caprofen, celecoxib, diclofenac, dipyrone, etodolac, flosulide, flurbiprofen, FR 140423, ibufenac, ibuprofen, indomethacin,

ketoprofen, ketorolac, lornoxicam, loxoprofen, lysine clonixinate, M-5011, meclofenamic acid, meloxicam, metiazinic acid, nabumetone, naproxen, NS-398, numesulide, oxyphenbutazone, D-penicillamine, phenylbutazone, piroxicam, pyrazolone, rofecoxib, salsalate, salicylate, SC-58236, SC58560, sulfasalasine, sulindac, tiaprofenic acid, tenidap, tenoxicam, tepoxalin, tolfenamic acid, tolmetin and zaltoprofen.

3. (Amended) The [combination] pharmaceutical composition according to claim [1 or] 2, [characterized in that the combination is with the NSAID] wherein said non-steroidal anti-inflammatory drug is ibupofen.

9. (Amended) A method for [the treatment of] treating a headache in a subject, [which method comprises treating] comprising:

administering to said subject an effective amount of mirtazapine in combination with paracetamol or [an NSAID] a non-steroidal anti-inflammatory drug.

10. (Amended) A method of [treatment of] treating a headache in a subject according to claim 9, [comprising administration of an amount of mirtazapine, charactereized in that] wherein the amount of mirtazapine is between 0.1 and 5 mg [mirtazapine].

11. (Amended) The method of [treatment of] treating a headache in a subject according to claim [3] 9, [characterized in that] wherein the headache is a tension-type headache.

12. (Amended) A patient pack for the treatment of a headache, comprising:

means for administration of metered dose units in combination with packaging material suitable for said dose units, [characterized in that] wherein the patient pack comprises mirtazapine, and [comprises] paracetamol or [an NSAID] a non-steroidal anti-inflammatory drug, and optionally, said packaging material is including means to help a recipient using the dose units most suitably for the treatment of a headache.

13. (Amended) [A] The patient pack according to claim 12, [for the treatment of headache comprising means for administration of metered dose units in combination with packaging material suitable for said dose units, characterized in that] wherein the dose units comprise pharmaceutical auxiliaries and mirtazapine in an amount between 0.1 and 5 mg [and optionally, said packaging material is including means to help a recipient using the dose units most suitably for the treatment headache].

Claims 14-17 have been added.